

### REMARKS

Claims 1 through 3 are pending in the application. All three claims stand finally rejected under 35 U.S.C. 102(a) as being anticipated by Chiesi et al (US 5,773,029).

Applicant's position that Chiesi et al does not anticipate the present claims because it does not disclose certain of the limitations in those claims (e.g., comparing, selecting, locating) was found not to be persuasive by the Examiner because the present claims do not set forth the target solubility of a specific salt or the solubility of specific salts in an aqueous cyclodextrin solution or specific steps of how the solubility of the salts are measured.

The failure of the present claims to set forth the features mentioned by the Examiner is not believed to be pertinent to a determination of whether certain elements of the rejected claims are disclosed in the Chiesi et al reference so as to anticipate those claims. Since Chiesi does not disclose locating a salt having a solubility greater than or equal to a target solubility (as required by claim 1), or the comparison/selection steps of claims 2 and 3, Chiesi can not anticipate claims 1-3.

Concerning the Examiner's comments about the present claims not setting forth the target solubility of a specific salt or the solubility of specific salts in an aqueous cyclodextrin solution, it would not be appropriate to include such information in the claims since these solubility figures will vary depending upon user-selected parameters. The target solubility, for example, may be any solubility figure desired by the user of the claimed methods. The term as specified in claims 1 and 2 is "desired target solubility", and that phrase is defined and exemplified on page 4 of the specification, lines 25-32, to clearly show that the figure will vary according to the user's needs such as dosage, dosage form and dosing regimen needs.

Also, the solubility of specific salts in aqueous cyclodextrin soln can vary from salt to salt and from one cyclodextrin to another. The present method claims are not limited to any particular medicinal compound, or any particular salt of any particular compound, or any particular dosage or dosage form or dosing regimen.

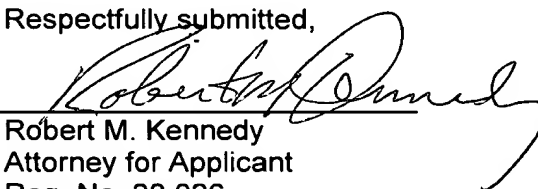
Concerning the Examiner's comments about the present claims not setting forth the specific steps for determining the solubilities of the salts, the carrying out of

determinations of solubility is well within the skill of the art, and therefore a specific methodology for doing so need not be included in the claims. Furthermore, solubility testing is described in detail in the specification (using, for illustration purposes, salts of ziprasidone and 40% aqueous solutions of the cyclodextrins SBECD and HPBCD) on page 10, line 19 to page 13, line 20. Therefore, there is no need for the claims to set forth specific details for carrying out the step of determining the equilibrium solubilities of the salts in view of the state of the art and Applicant's teachings in the specification. Moreover, including such details in the claims would unnecessarily add easy-to-avoid limitations and result in Applicant's getting very little protection for the invention, which contemplates the use of any methodology for determining solubility that is available to the skilled artisan.

In view of the comments above, it is respectfully requested that the rejection of claims 1-3 under 35 U.S.C. 102(a) as being anticipated by Chiesi et al be reconsidered and withdrawn.

Date: 12/16/04

Respectfully submitted,

  
Robert M. Kennedy  
Attorney for Applicant  
Reg. No. 28,026

Pfizer Inc  
Patent Department  
Eastern Point Road  
Groton, CT 06340  
(860) 715-5303